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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,579	08/30/2001	Vladimir Pavlovic	200302031-1	9433

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IP ADMINISTRATION  
LEGAL DEPARTMENT M/S 35,  
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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/943,579

Applicant(s)

PAVLOVIC ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-12 is/are rejected.
- 7) ☒ Claim(s) 1-6, 8 and 10-12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

### ***Election/Restrictions***

Applicant's election of gene locations which include exons only in the response filed 10/24/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 7 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in a response filed 10/24/03.

### ***Information Disclosure Statement***

The IDS's filed 8/30/01 and 1/10/02 have been considered in full.

### ***Specification***

The amendment filed 1/18/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

On page 2, lines 5-9 of the amended paragraph are new matter. The originally filed specification disclosed that each protein has a "unique function", not a "well-defined" functionality. The terms "unique" and "well-defined" are not equivalent, and one skilled in the art would not recognize that substitution of one term is merely a "correction" for another (e.g. as would be the case wherein a term is mistranslated from

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a foreign language). While the originally filed specification disclosed that DNA sequences include protein-coding sequences and non-coding function sequences, the originally filed specification did not disclose anywhere that these are "biologically distinct regions", nor that a DNA molecule comprises "many" biologically distinct regions. Nowhere did the originally filed specification or claims teach or recite distinguishing between "intergenic DNA and genes" nor that genes in mammalian cells may be called split genes. The originally filed specification taught, on page 2, that "there are protein-coding sequences (genes), called "exons", and non-coding-function sequences called "introns" interspersed within many genes." A teaching that protein-coding sequences are called exons is not the same as a teaching that coding sequences in a gene are *contained within exonic regions*. Further, a teaching that exons and introns are "interspersed" is not the same as a teaching that "exonic regions" are *sequentially separated* by introns.

On page 3, line 19 disclosed "Human chromosome 22". The amended paragraph on page 3 newly discloses genomes including "Human". The deletion of "chromosome 22" causes the paragraph to include the entire human genome, not just chromosome 22. Nowhere did the originally filed disclosure teach anything with regard to the entire human genome.

On page 7, line 3 newly recites that "ligated exons form a sequence". The originally filed specification did not teach "ligated exons" nor "formation" of a sequence by such exons, anywhere.

On page 8, line 4 newly discloses that predictions of the inventive system will have the potential "to refine boundaries" in order "to verify predictions" made by "experts". The originally filed specification disclosed that predictions of the inventive system will have the potential "to generalize to genes" which are "undiscovered" by "*any* of the *individual* experts" (emphasis added by examiner). A teaching for *generalization* of data is not the same as "refining" boundaries (between gene regions?), nor is a teaching for generalizing (or finding?) "undiscovered" genes the same as "verifying a prediction. The originally filed paragraph appeared to teach that the inventive system, by combining data from various expert systems, could be used to predict/identify genes which were not predicted/identified by a single or individual expert system. The amended paragraph appears to teach something very different - that the inventive system may be used merely to verify and refine boundaries (between exons and introns?) previously predicted by multiple expert systems. While the totality of the specification indicates that the inventive method and system can be used to improve prediction by increasing the accuracy of exon prediction (see pages 15-16) by combining data from multiple expert systems, the originally filed specification did not teach anywhere that the inventive system is one which "verifies" and "refines" boundaries. It is noted that a "boundary" is not defined anywhere in the originally filed specification.

On page 10, line 9 newly discloses finding a distribution of "one or more random variables" in a network. Originally filed page 10 disclosed, at line 9, a distribution of "a

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random variable". The originally filed specification did not disclose finding a distribution of multiple variables in a network.

On page 11, line 17 newly defines  $y$  as a "combined prediction". Originally filed page 11, at line 16, defined  $y$  as "the ground truth". In Equation 1 on original page 11, the "combined prediction 33 is denoted  $Y$ "; however, it is not clear if the " $Y$ " of Equation 1 (line 8) is the same as the " $Y$ ", defined to be "the ground truth" of the equation disclosed in line 13.

On page 14, line 8-9 newly disclose that an expert system may label a nucleotide  $I$  if it belongs to an introns "or an intragenic region". Originally filed page 6 disclosed that predicted locations for genes are indicated by exons and introns, original page 9 disclosed exon/intron predictions, and original page 14 disclosed labeling for an exon and for an introns. Original claims 6 and 7 recited gene locations which include exons, or exons and introns. The originally filed specification and claims were silent with regard to "intragenic regions".

On page 15, lines 11-12 newly disclose that "Wrong exon (WE) prediction implies the prediction has no overlap with a true exon." The originally filed specification taught, on page 15, line 8-9 that an exon is "missed" if there is no overlap with a predicted exon, and on line 10, that "WE gives the percentage of wrongly or overpredicted exons". The originally filed specification did not teach anywhere that a "wrongly or overpredicted exon" is the same as a "missed exon". In fact, since "ME" is also defined on page 15 as the percentage of "missed" exons, it is unclear, in view of the amendment, just what each term actually represents.

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Applicant has not pointed to support in the originally filed specification or claims for the newly added material of the specification, and none is apparent, as set forth above. For these reasons the amendment to the specification introduces new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

The disclosure is objected to because of the following informalities: On page 4, line 20, the term "exon)<sub>n</sub> should be --exon)<sup>n</sup>--..

Appropriate correction is required.

### ***Claim Objections***

Claim 1-6, 8 and 10-12 are objected to because of the following informalities:

Claim 1 should begin with --A--; each of claims 2-8 and 10-13 should begin with --The-- . Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

An apparatus or method comprising a Bayesian network which predicts an intergenic region is new matter. Original claims 4 and 10 recited an equation comprising the term  $I$ , but did not define the term. The originally filed specification, on page 6, disclosed that predicted locations for genes are indicated by exons and introns, original page 9 disclosed exon/intron predictions, and original page 14 disclosed labeling for an exon and for an introns. Original claims 6 and 7 recited gene locations which include exons, or exons and introns. The originally filed specification was silent with regard to "intragenic regions". Applicant does not point to support in the originally filed specification or claims for the amendment filed 1/18/02, and none is apparent for the reasons set forth herein, therefore claims 4 and 10 recite new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a plurality of units "providing" indications of gene locations "output" by the units. These appear to be method steps; however, claim 1 is directed to a system (apparatus). It is unclear whether applicant intends a method, or perhaps intends a system comprising a program or instructions for performing the apparent



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method steps, therefore the claim is indefinite. If applicant intends merely a system comprising units, then it is further unclear what structural limitation of the system is intended by the "intended use" apparently recited for the units.

Claim 1 recites a combiner "being formed of a Bayesian network". It is unclear if applicant is intending to recite a method step or intends to recite a limitation of the combiner, therefore the claim is indefinite. Further, it is unclear if the "combiner" is intended to comprise a Bayesian network, or to produced by formation of a Bayesian network (i.e. limited by its method of making?), or if the combiner is intended to produce a result which is or comprises a Bayesian network, therefore the claim is further indefinite.

Claim 1 recites a Bayesian network "which combines" predicted gene locations "using" probabilities. Again, these appear to be method steps, and it is unclear what limitation of the system is intended. Further, it is unclear what step or limitation is intended by the terms "combining" and "using". These terms may have many meanings in the art and are not specifically defined by the specification. For example, "combining" may mean physical or virtual attachment or rearrangement (e.g. of a string of characters or sequence), adding, multiplying, stacking, arranging in geometric shapes, etc. For these reasons, the claim is indefinite.

Claim 1 recites the phrase "and forming" line 8. It is unclear whether this is intended to be a method step or a limitation of the system, therefore the claim is indefinite. Further, it is unclear what is intended to be "forming" a final combined output; i.e. the combiner, or the Bayesian network, therefore the claim is further indefinite.

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Claim 3 recites that the Bayesian network "accounts for" dependencies. It is unclear what limitation is intended by the phrase "accounts for", therefore the claim is indefinite.

Claim 8 recites that the Bayesian network "is trained on" known genes. It is unclear if this intended to be a method step or a limitation of the system, therefore the claim is indefinite. Further, it is unclear what structural or functional limitation of the network is intended by the "training", therefore the claim is further indefinite.

Claim 9 recites a step of "using" a plurality of expert systems and of "using" a Bayesian network, but does not recite an explicit method step. The term "using" has a plethora of meanings in the art and is not specifically defined by the specification. Also, as the term is applied to two different nouns, it appear to have different meanings in the claim. As it is unclear what method steps are actually intended, the claim is indefinite.

Claim 9 recites that a Bayesian network "accounting for" dependencies. It is unclear what limitation is intended by the phrase "accounting for", therefore the claim is indefinite. Further, it is unclear is applicant intends to recite a separate method step, or intends to limit the network, therefore the claim is indefinite.

The examiner recommends that the claims be rewritten to clearly reflect all intended claim limitations. All intended methods steps should be recited as positive, active steps separated by line indentations.

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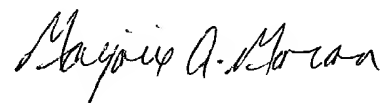
**Conclusion**

Claims 1-6,8-12 are rejected; claims 7 and 13 are withdrawn. The specification and claims 1,6, 8, and 10-12 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0549.



Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

mam